

Spring 2009

# Nanotechnology Law Report

Legal Issues Surrounding Nanotechnology & General Nanotechnology News & Events

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## EPA Issuing Significant New Use Rules for Two Nanomaterials

There has been a significant debate over the past few years regarding whether nanoscale materials should be treated as existing chemical substances, new chemical substances, and/or significant new uses of existing chemical substances for purposes of the Toxic Substances Control Act (TSCA). A core issue in this debate has been whether -- because of small size and sometimes unique properties -- the U.S. Environmental Protection Agency (EPA) should treat all nanoscale materials as "new" chemicals under TSCA and subject them to TSCA's premanufacturing notice and approval requirements even if their bulk counterparts are already on TSCA's inventory of approved chemical substances.

An important sibling issue is whether the use of some nanoscale materials in certain circumstances constitutes a "significant new use" of an existing chemical substance that also triggers TSCA's premanufacturing notice and approval requirements.

EPA recently took a large step toward addressing the significant new use issue when it announced two separate significant new use rules (SNURs) for siloxane modified silica and alumina nanoparticles. Each chemical substance had been the subject of a prior pre-manufacturing notice (PMN).

In the Federal Register Notice announcing the impending SNURs, EPA stated that dermal and inhalation exposures of the substances were not expected under the

uses outlined in the PMNs and declined to determine whether the substances actually posed unreasonable risks. On the other hand, EPA found that "[b]ased on test data on analogous respirable, poorly soluble, particulates, EPA has concerns for lung effects for the PMN substance(s). Based on physical properties, EPA has concerns for potential systemic effects from dermal exposure to the PMN substance(s)."

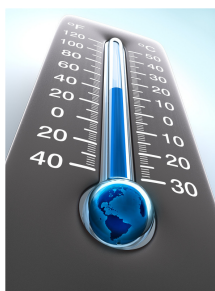
The proposed SNURs also came with use restrictions: "EPA has determined, however, that use without impervious gloves or a NIOSH-approved respirator with an APF of at least 10; the manufacture, process, or uses of the substance(s) as a powder; or uses of the substance(s) other than described in the PMN may cause serious health effects." Accordingly, manufacturers of the chemical substances must ensure that their employees wear NIOSH approved respirators and gloves when working with the substances and prohibit working with the substances in powder form or using them other than in additive applications.

Thus, in a unique twist, one of the significant new uses being regulated by EPA is use of the chemical substances without appropriate personal protective equipment. While creative, the approach avoids determining the primary issue -- are the substances hazardous or not for TSCA purposes?



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## Interim Report: Lukewarm Response to EPA's Nanoscale Material Stewardship Program



The U.S. Environmental Protection Agency (EPA) published an interim status report in January 2009, regarding the initial industry participation in its Nanoscale Materials Stewardship Program (NMSP). A final report is expected in early 2010.

*Nanoscale Materials Stewardship Program, Interim Report, January*

*2009, U.S. Environmental Protection Agency, Office of Pollution Prevention and Toxics.*

At the outset, EPA noted that “[t]he findings and conclusions [of the] report should not be construed or interpreted to represent any Agency regulatory or statutory guidance or statement of official Agency policy.” Several companies submitting NMSP data should be relieved by this disclaimer, as EPA identified 18 nanoscale materials in NMSP submissions that may be considered new chemical substances under the Toxic Substances Control Act (TSCA) and, therefore, subject to premanufacturing notice requirements. Whether EPA takes any enforcement steps in this regard remains to be seen.

Getting to the highlights of the report, EPA concludes that the NMSP has (thus far) produce mixed results:

- “In the aggregate, the NMSP has sufficiently advanced EPA’s knowledge and understanding to enable the Agency to take further steps towards evaluating and, where appropriate, mitigating potential risks to health and the environment.”
- “It appears that nearly two-thirds of the chemical substances from which commercially available nanoscale materials are based were not reported under the Basic Program.”
- “It appears that approximately 90% of the different nanoscale materials that are likely to be commercially available were not reported under the Basic Program.”
- “The low rate of engagement in the In-Depth Program suggests that most companies are not inclined to voluntarily test their nanoscale materials.”

EPA’s overall conclusion is that:

- “[T]he NMSP can be considered successful. However, a number of the environmental health and safety data

gaps the Agency hoped to fill through the NMSP still exist. EPA is considering how to best use testing and information gathering authorities under [TSCA] to help address those gaps.”

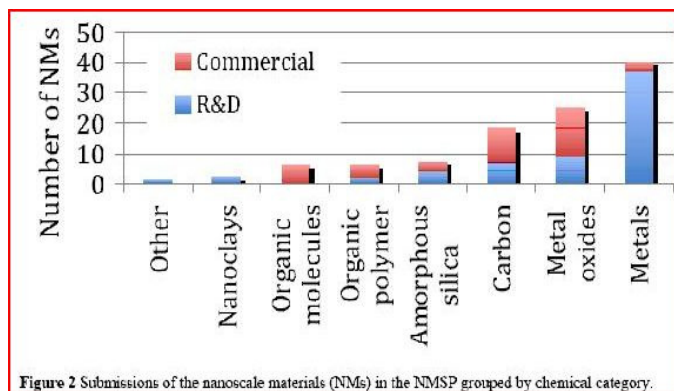
Our view is that response to the NMSP has been lukewarm, at best.

### Analysis of Current Submissions

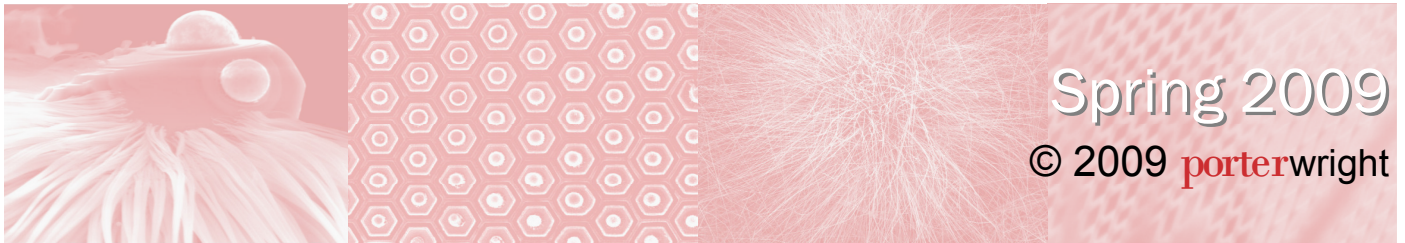
As of December 8, 2008, information under the Basic Program had been submitted by 29 companies/associations, covering 123 nanoscale materials. Seven additional companies had also committed to submitting data under the Basic Program at some future date.

The In-Depth Program had commitments from four companies. Additionally, the American Chemistry Council expressed an interest in coordinating future In-Depth data submissions.

A chart from the interim report breaking down Basic Program submissions by material type follows. Nanoscale metals and metal oxides predominate. Many of these materials are still in the research and development stage.



Beyond numbers and types of nanoscale materials, EPA also noted that “very few submissions provided either toxicity or fate studies.” This lack of information provides EPA with several challenges in meeting the NMSP’s basic goal of determining whether certain nanoscale materials or categories of materials may present risks to human health and the environment. No doubt these challenges have contributed to EPA’s recent attempt to use consent orders and significant new use rules under TSCA to generate animal inhalation toxicity data.



### An Ill-Fated Comparison

As apparent justification for the lack of number and quality of submissions, EPA compared the information it received under the NMSP with the information available in two publicly available databases: Nanowerk's Nanomaterials Database and the Project on Emerging Nanotechnologies Inventory of Nanomaterials in Consumer Products (PEN).

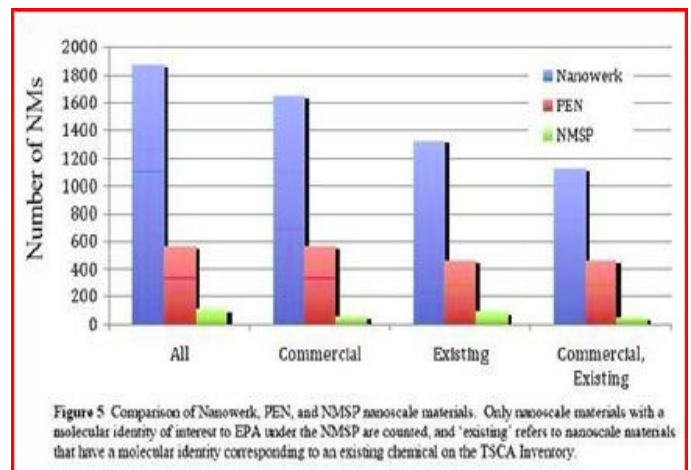
EPA selected these two databases because "[a]s far as EPA is aware, there is no comprehensive database of nanoscale materials, which is a critical need for better understanding the universe of commercially available nanoscale materials." Unfortunately, neither database surveyed by EPA was designed for this purpose (although we are big fans of both). Using these databases in this manner further points out the difficulties facing EPA. Simply put, both Nanowerk and PEN appear to have far better informal data collections than EPA's formal collection – an unacceptable condition.

Nonetheless, EPA's search of the Nanowerk database identified 2,084 potential nanoscale materials, which EPA then condensed to a list of 1332 potential submissions by excluding new chemical substances under TSCA (e.g./ carbon nanotubes and fullerenes), eliminating materials in which it has no interest, and grouping together materials with the same molecular identity. EPA then identified 55 commercially relevant chemicals from this truncated list. Comparing EPA's NMSP submissions to this list does not look so bad. EPA, however, provided no good reason for

excluding new chemical substances from its analysis, nor did it make a convincing case that it can consistently determine molecular identity from Nanowerk's database.

A similar analysis of PEN's database identified 566 nanoscale materials, out of which EPA found that 48 are commercially relevant chemicals.

It is clear that despite all of this winnowing, the amount and quality of data submitted thus far under the NMSP is dwarfed by that available in both the Nanowerk and PEN databases. Given this situation, it is hard to imagine that advocacy groups will remain muted until EPA's final NMSP report is released in 2010. Another table from the report summarizing this data comparison follows.



## NNI Reauthorization--Here We Go Again



In February 2009 the House of Representatives overwhelmingly passed its version of the National Nanotechnology Initiative (NNI) reauthorization amendments, H.R. 554. The passage was by "voice vote," meaning there is no record of who may have voted for or against the reauthorization. This is the next step toward complete reauthorization of the

NNI statute, which was first enacted in 2003.

According to the House Science and Technology Committee: "H.R. 554 requires that the NNI agencies develop a plan for the environmental and safety research component of the program that includes explicit near-term and long-term goals, specifies the funding required to reach those goals, identifies the role of each participating agency and includes a roadmap for implementation."

H.R. 554 also includes provisions aimed at capturing the economic benefits of nanotechnology. "In 2007, \$60 billion in nano-enabled products were sold; it is predicted that the number will rise to \$2.6 trillion by 2014. To encourage commercialization in the U.S. – and the corresponding economic benefit – the bill strengthens public-private partnerships by encouraging the creation of industry liaison groups to foster technology transfer and to help guide the NNI's research agenda. The bill also promotes the use of nanotechnology research facilities to assist companies in the development of prototypes."

Recall that we have been down this road before. The 110th House passed identical reauthorization language, H.R. 5490, only to have it expire at the end of the Senate's term last year. Hopefully, the Senate completes the reauthorization process more quickly this time around.



## Honda Op-Ed on National Nanotechnology Initiative Reauthorization

Rep. Michael Honda (D-CA) published an op-ed piece in the San Jose Mercury News in March 2009, focusing on his bill, H.R. 820, introduced in the House on 02/03/2009, and on his support for Rep. Gordon's (D-TN) bill, H.R. 554, which has passed the House and been referred to the Senate. Rep. Honda's op-ed also focuses on the potential benefits of nanotechnology, ranging from

improved transportation to helping to clean the environment. Rep. Honda further reminds readers that his bill calls for a public-private partnership between the federal government and private industry to establish guidelines for responsible development. Rep. Honda's op-ed may be read at [http://www.mercurynews.com/opinion/ci\\_11837367](http://www.mercurynews.com/opinion/ci_11837367).

## US/UK Nano-EHS Research Partnership Announced



In December 2008, the U.S. Environmental Protection Agency's (EPA) National Center for Environmental Research and the United Kingdom's Natural Environment Research Council, Physical Sciences Research

Council, Department for Environment, Food and Rural Affairs (DEFRA) announced a "joint research effort to develop and validate predictive tools and similar conceptual models that predict exposure, bioavailability and effects of manufactured nanomaterials in the environment." The organizations are expected to issue a joint call to interested parties for the submission of predictive models that

will then be evaluated by both countries. The models will likely cover "environmental fate, behaviour, interaction, bioavailability and effects focused on one or more classes of manufactured nanomaterials," as well as new detection methods and other topics.



In the ongoing quest to close the "data gap," this appears to be another useful partnership where two worldwide leaders in nanotechnology development – EPA and DEFRA – are combining resources and efforts to better understand the possible environmental impacts of nanomaterials.

## European "Framing Nano" Report

A new European report adds additional perspective to current nano-regulatory questions. The Swiss-based Innovation Society recently released its report: "Framing Nano Mapping Study on Regulation and Governance of Nanotechnology."



The 138-page report examines nanotechnology regulatory actions worldwide, including European, North American, and Asian efforts. The report looks to the voluntary and regulatory efforts in individual countries (or the EU as appropriate), and particularly focuses on environmental health and safety and ethical, legal and societal issues. It notes, "[t]here is a general agreement among these stakeholders on the principal problems facing nanoregulation and their priorities. In particular:

- The major source of concern regarding potential risks of nanotechnology are, at the moment, 'free' manufactured nanomaterials;

- There is an urgent need to develop, at least for some specific nanomaterials, new approaches and methods for their risk assessment and to improve the knowledge base on their characteristics and behaviour; and
- There is a need for an international approach to the management of nanomaterials risks, with a particular emphasis on the development of harmonised standards and guidance, and on an effective engagement of all stakeholders."

The report ultimately states that "nanoregulation must be regarded as a dynamic affair which must adapt to the evolution of the scientific knowledge and applications and public attitude. A continuous updating must be part of the governance of nanotechnology."

The Framing Nano project is ultimately working toward proposing a governance plan for regulating nanotechnology at the EU level.

## California Formally Requests Carbon Nanotube Information From Manufacturers



On January 22, 2009, California's Department of Toxic Substances Control (DTSC) sent a formal request to several California manufacturers and/or importers of carbon nanotubes seeking information regarding

analytical test methods, environmental fate and transport, and other relevant environmental, health, and safety information regarding carbon nanotubes. The request was issued by DTSC under the authority granted by California's Health and Safety Code 699, Sections 57018-57020.

DTSC asked manufacturers to answer the following questions:

- What is the value chain for your company? For example, in what products are your carbon nanotubes used by others? In what quantities? Who are your major customers?
- What sampling, detection and measurement methods are you using to monitor (detect and measure) the presence of your chemical in the workplace and the environment? Provide a full description of all required sampling, detection, measurement and verification methodologies. Provide full QA/QC protocol.
- What is your knowledge about the current and pro-

jected presence of your chemical in the environment that results from manufacturing, distribution, use, and end-of-life disposal?

- What is your knowledge about the safety of your chemical in terms of occupational safety, public health and the environment?
- What methods are you using to protect workers in the research, development and manufacturing environment?
- When released, does your material constitute a hazardous waste under California Health & Safety Code provisions? Are discarded off-spec materials a hazardous waste? Once discarded are the carbon nanotubes you produce a hazardous waste? What are your waste handling practices for carbon nanotubes?

Recipients have one year to supply the requested information.

Regular readers will recall that similar efforts were considered by Berkeley, California and Cambridge, Massachusetts. We helped peer-review Berkeley's disclosure guidelines and were on Cambridge's advisory committee which evaluated the City's regulatory options. We are also currently helping coordinate some of the responses to California's data request. Please call or e-mail us for further details.

## New Nano-Product Registry and Label

Nanosafe, Inc. recently announced the launch of its new website, the Nanotech Register and its new product labeling system, Nanosafe Tested. The Nanosafe Tested program is designed "to provide clients with independent third-party testing of nanotechnology products." Specifically, "Products that have been NANOSAFE TESTED are subjected to defined testing criteria developed from peer-reviewed literature and comparable standardized testing methods. Test results are reported in two ways: first, a comprehensive, proprietary test report is provided to the client; second, a one-page, non-proprietary summary report is posted to the NANOTECH REGISTER where it may be viewed freely by the general public." The only product on the Registry to this point is the XPert® Nano™ System

by LABCONCO INC.

This is the second (or third, depending on how you count) registry that is available to the public at this stage (if you know of more, please let us know!). In addition to the Nanosafe Registry, there is also the Nanomark system in Taiwan [<http://www.nanomark.itri.org.tw/Eng/>], which has a similar goal. While still in its early stages, having an additional registry should be helpful for tracking and continuing to evaluate nanomaterials on the market.



## UPDATE: Canada Regulation of Nano

CBC News reported in January that Environment Canada anticipates enacting a national reporting regulation covering nanotechnology later in the Spring of 2009. While Environment Canada would not comment directly on the report, CBC stated that, "Department officials said the plan is to send out a notice that requires companies and institutions that used more than one kilogram of nanomaterials in 2008 to provide information to the government." The CBC release also indicated that Environment Canada has been "negotiating with private industry" for more than one year concerning nanotechnology regulation in Canada.

Another statement of note from the article is that "Officials said this request for information under the Canadian Environmental Protection Act does not require companies to submit information beyond 2008. However, Ottawa could make similar requests for such information in the future." The identity of the actual "officials" making these statements remains unknown, but we seem to be getting closer to the regulatory action becoming reality.



Sally Tinkle (National Science and Technology Council):

"There is still concern over exposure to nanoparticles at the end of the products' life cycles, even if companies design the product to be completely safe for the immediate user. Once [a nano-enabled item] is thrown out and begins to decompose or degrade—or it begins to break down from day-to-day use—the particles can be released into the environment. Care needs to be taken to control the exposure throughout the product life cycle."

*From C. Schmidt, Environmental Health Perspectives, Nanotechnology-Related Environmental, Health, and Safety Research: Examining the National Strategy (April 2009).*

## Nanotechnology Health and Safety Forum -- June 8 - 9, 2009

Battelle Memorial Institute, the University of Washington, and the University of Oregon are co-sponsoring an international Nanotechnology Health and Safety Forum (NHSF) in Seattle, Washington on June 8 - 9, 2009. The NHSF is coinciding with the first world-wide meeting of the International Organization for Standardization (ISO) TC 229 -- Nanotechnologies group taking place in the United States.



Topics covered at the NHSF will include:

- **The EHS Progress Report:** today's status and tomorrow's next steps;
- **International Standards:** developing a timeline & milestones;
- **Navigating Regulations:** encouraging dialogue between Europe, Asia, and the U.S.;
- **Safety Guidelines:** state of the science and recommended occupational safety guidelines for working with nanomaterials;

- **Managing Risk:** the insurance industry perspective; and

- **What's New:** current activities of innovative nano-manufacturers.

John Monica has been invited to speak on the insurance/managing risk panel along with speakers from Zurich North America and Chubb Insurance:

*The availability of insurance for entities using nanotechnology is critical to the further development and application of nanomaterials in industry. Yet the widening use of nanotechnology (while toxicology remains to be determined) is a central concern for the global insurance industry. Insurance, Nanotechnology, and Risk addresses the prospects for managing nano risk through the perspectives of a Silicon Valley loss control specialist, a major international underwriter, and liability/coverage counsel.*

This should be a great conference with an international focus; plus, Seattle in June is going to be a lot of fun.



## “Regulation and Risk Assessment of Nanomaterials – Too Little, Too Late?”

Steffen Foss Hansen is a Ph.D. candidate at the Technical University of Denmark’s Department of Environmental Engineering. We recently posted a copy of his well-written Ph.D. thesis – “Regulation and Risk Assessment of Nanomaterials – Too Little, Too Late?” on our website: <http://www.nanolawreport.com/2009/03/articles/regulation-and-risk-assessment-of-nanomaterials-too-little-too-late>.

Dr. Hansen’s thesis investigates whether existing environmental, health, and safety regulations (EHS) and risk assessment techniques are adequate for nanotechnology and provides “some recommendations on how to govern



nanotechnologies.” Although we do not always agree with Dr. Hansen on nano-related EHS issues, there is no doubt that his work is detailed, thorough, and thought provoking.

As an aside, we also had the pleasure of contributing with Dr. Hansen and others to a nanogovernance book chapter this past year, which might be of interest to Nanolawreport readers:

*Considerations for Implementation of Manufactured Nanomaterial Policy and Governance*, NANOMATERIALS RISKS AND BENEFITS, NATO Science for Peace and Security Series C: Environmental Security, (Igor Linkov and Jeffery Steevens eds., Springer 2008).

## New Yale Public Opinion Study Regarding Nanotechnology Safety



Nanowerk recently reported on a new public opinion study released by Yale University concerning the safety of nanotechnology. The study is reported fully in *Nature Nanotechnology*.

The Yale study concludes that an individual’s view on how safe nanotechnology is, or is not, is based largely on their pre-existing cultural values. As Dan Kahn, lead author, explains, and Nanowerk reports, “People who had more individualistic, pro-commerce val-

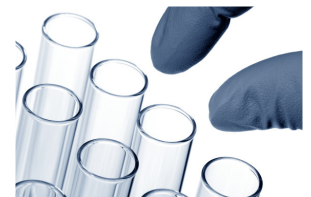
ues, tended to infer that nanotechnology is safe...while people who are more worried about economic inequality read the same information as implying that nanotechnology is likely to be dangerous.” Views on nanotechnology seem to correlate to views on other issues such as global warming. The study goes on to conclude that communication with the public remains important and that perhaps the dialogue should account for the existing predispositions of the audience.

## FDA Announces Collaborative Effort with Alliance for NanoHealth

At the beginning of March 2009, the U.S. Food and Drug Administration (FDA) posted a press release announcing a “collaboration initiative” with the Alliance for NanoHealth (ANH) ([www.nanohealth.org](http://www.nanohealth.org)). FDA and ANH will work together “to expand knowledge of how nanoparticles behave and affect biologic systems and to facilitate the development of tests and processes” to lower possible risks that might be associated with nanoengineered products.

The “Memorandum of Understanding” between FDA and ANH, published in the Federal Register 03/13/2009 (72 FR 10927), makes it clear that this collaboration has two major goals:

- “Moving nanoengineered medical products from the preclinical stages of development through clinical stages and then to commercialization.”
- “Understanding the risks and benefits of nanoengineered medical product development to the extent that this information can facilitate the regulatory review and evaluation of new medical products that incorporate nanotechnology.”



## Nanotechnology Conference: Food & Drug Law Institute

The Food & Drug Law Institute held its 2nd Annual Conference on Nanotechnology Law, Regulation and Policy on February 18 - 19, 2009 at the L'Enfant Plaza Hotel in Washington, DC.

Topics included:

- What progress is FDA making in implementing its Nanotechnology Task Force Report?
- What can FDA learn from EPA and other oversight agencies of the National Nanotechnology Initiative (NNI)?
- Will the Democratic Congress invest in and/or regulate nanotechnology more than the Bush Administration?
- Are workers exposed to asbestos-like dangers from dealing with nano products?
- How does a responsible company devise a risk man-



agement plan for nanotech development – one that takes into account OSHA and NIOSH policy?

- What is reasonable and required federal funding for U.S nanotechnology R&D, including monies for safety and social policy research?
    - Are China and Japan ahead of the U.S. in nanotech development?
    - For nanotech products and processes, should particle size make a regulatory difference?
- John Monica spoke on the Data Call-in for Carbon Nanotubes recently issued by California's Department of Toxic Substances Control and commented on both the legitimate aspects of the Data Call-in as well as some of its substantial flaws.
- You can download PowerPoint presentations from the conference at <http://www.fdpi.org/conf/454/index.html>.

Jim Willis (EPA OPPT): Speaking about the response thus far to EPA's Nanoscale Stewardship Program: "On the one hand, we thought it was pretty good responsiveness for a volunteer program." "On the other, we know there are hundreds of other nanomaterials that weren't reported. And that indicates clearly that we need to do more if we want to get a better handle on what's being produced, at what levels, and how humans are being exposed." From C. Schmidt, *Environmental Health Perspectives, Nanotechnology-Related Environmental, Health, and Safety Research: Examining the National Strategy (April 2009)*.

## Responsible Nanotechnology: Turning Vision into Reality



The Organization for Economic Cooperation and Development's (OECD) Business and Industry Advisory Committee's (BIAC) expert group on nanotechnology recently issued a "vision paper" which attempts to identify "strategic priorities from the perspective of the OECD Business Community."

"It is meant to serve as a guidance to both the private and public sectors" in achieving further development of nanotechnology. In particular, the report focuses on six areas that BIAC believes should be considered in present and future nanotechnology debates:

- Energy;
- Food and agriculture;
- Healthcare;
- Water treatment;
- Information and communications; and

- Pollution remediation.

The report also considers "some of the key issues that will increasingly affect nanotechnology development in coming years:"

- Environmental, health & safety issues;
- Responsible development;
- Human resources (training and education would have been a better way of putting it);
- Intellectual property and patent protection; and
- Marketing & consumer issues - public trust.

BIAC concludes its report by urging the OECD to address priority areas ranging from the development of standardized hazard and risk assessment procedures to an assessment of public attitudes toward nanotechnology and nanomaterials. The report may be accessed at [http://www.biac.org/news/90204\\_nanotech\\_vision\\_paper.htm](http://www.biac.org/news/90204_nanotech_vision_paper.htm).



## NIST Call for White Papers

The National Institute for Standards and Technologies (NIST) recently issued a call for white papers “to support, promote, and accelerate innovation in the United States through high-risk, high-reward research in areas of critical national need.” The call was issued through NIST’s Technology Innovation Program (TIP) and covers a multitude of areas, including nanotechnology and nanomaterials.

“In this call for white papers, TIP is seeking information in all areas of critical national need, but also seeks information to assist TIP in further defining several topic areas under development. White papers may discuss any area of critical national need of interest to the submittee or may

address any of the following topic areas: civil infrastructure, complex networks and complex systems, energy, ensuring future water supply, manufacturing, nanomaterials/nanotechnology, personalized medicine, and sustainable chemistry.”



More information on submitting White Papers to TIP can be found at [http://www.nist.gov/tip/guide\\_for\\_white\\_papers.pdf](http://www.nist.gov/tip/guide_for_white_papers.pdf). The remaining deadlines for submission are May 11 and July 13, 2009.

## “Nada Known about Nano” - OMB Watch article



A recent article on OMB Watch examines state and federal efforts to collect information about nanotechnology’s impact on health and the environment. The State of California “appears to be the furthest along in collecting information about the po-

tential impacts of nanotechnology,” particularly the efforts of the California Department of Toxic Substances Control, [http://www.dtsc.ca.gov/TechnologyDevelopment/Nanotechnology/index.cfm#Why\\_is\\_DTSC\\_interested\\_in\\_nanotechnology?](http://www.dtsc.ca.gov/TechnologyDevelopment/Nanotechnology/index.cfm#Why_is_DTSC_interested_in_nanotechnology?). The OMB Watch article may be accessed at <http://www.ombwatch.org/node/9726/>.

## The Impact of Toxicity Testing Costs on Nanomaterial Regulation



A recent study – “The Impact of Toxicity Testing Costs on Nanomaterial Regulation” – takes the position that the United States has placed “the entire burden of data collection and risk assessment...on agencies without the budgetary means to carry out this mandate.” According to the

article, the U.S. Environmental Protection Agency (EPA) and the Occupational Safety and Health Administration, the agencies largely involved in nano-EHS data collection, simply do not have the funds to do the jobs they have been assigned by law. The testimony of John Stephenson before the House Committee on Energy & Commerce’s

Subcommittee on Commerce, Trade, and Consumer Protection hearing “Revisiting the Toxic Substances Control Act of 1976” (Feb. 26, 2009) reinforces this by stating that the EPA is dependent on chemical companies voluntarily supplying data about their products. Mr. Stephenson’s testimony, along with other witnesses’ prepared testimony, may be found at [http://energycommerce.house.gov/index.php?option=com\\_content&task=view&id=1505&Itemid=95](http://energycommerce.house.gov/index.php?option=com_content&task=view&id=1505&Itemid=95)

Both the article and Stephenson’s testimony come to the same general conclusion: a system such as the EU’s REACH program should be adopted, leading to a tiered structure of testing based on the release of materials into the atmosphere.

Günter Oberdörster (University of Rochester):

“I think there’s a certain amount of hype surrounding the toxicity issues.” “However, until we know better, we should be careful and avoid exposure. You can do a lot of in vitro testing at high doses and identify a hazard, but you need the necessary exposure for a risk to be present.”

From C. Schmidt, *Environmental Health Perspectives, Nanotechnology-Related Environmental, Health, and Safety Research: Examining the National Strategy* (April 2009).

## “Insurers scrutinize nanotechnology”

The March 2009 issue of Environmental Science & Technology published an article concerning the difficulties insurance companies face in assessing the risks in insuring manufacturers using nanomaterials in their products, particularly carbon nanotubes, due to a lack of reliable data on the potential effects of nanomaterials on the environment, workers’



health, and product liability.

While some companies have made the decision to exclude nanomaterials from coverage, companies such as Swiss Re and Lloyds of London are recommending that insurers issue short-term coverage as a way of avoiding latent claims. The article is available at <http://pubs.acs.org/doi/full/10.1021/es900041e>.

## “Nanoparticle toxicity doesn’t get wacky at the smallest sizes”

Science Daily recently carried an article about the increasing industrial use of nanosized silica particles and the claim that they have brought about a corresponding increase in questions about the possible toxic effects of these particles on human health. Currently, there is no consensus about what these effects might be. Brian Thall, a scientist at the Department of Energy’s Pacific Northwest

National Laboratory, made a presentation at the American Association for the Advancement of Science’s 2009 Annual Meeting in Chicago on nanosized silica particles and the cellular proteins to which they might attach and use to enter a cell. <http://www.sciencedaily.com/releases/2009/02/090214162629.htm>.

## Nanotechnology: Considering the Complex Ethical, Legal, and Societal Issues with the Parameters of Human Performance

“Nanotechnology: Considering the Complex Ethical, Legal, and Societal Issues with the Parameters of Human Performance,” by Linda MacDonald and Jeanann S. Boyce and published in Nanoethics 2: 265-275 (2008), is one of the more thought-provoking articles to examine the potential impacts of nanotechnology on law and society. It is certainly an ambitious article: “...we examine both the positive and negative aspects of the ethical, legal, and societal implications of using nanotechnology for human enhancement.”

“Human enhancement” for these authors covers a very broad spectrum, from possible use in the treatment of cancer to “restoring lost functions of limbs, senses and brain function.”

In a suprisingly short section discussing the potential negative aspects of nanotechnology in general and nanomedicine in particular, the authors do little more than list what they refer to as the perils ranging from “Neurnano Warfare” to economic upheaval.

The authors note that other articles have called for banning nanotechnology research and development, but take

the position that this is unlikely to happen for two reasons:

- “There is far too much money at stake.”
- “Such a ban would push research underground where it could not be regulated.”



The authors also note that “much of the focus in the legal area...has been on intellectual property, the preservation of property rights, [and] patent law.”

Finally, the authors make some recommendations on how the law should deal with nanotechnology, ranging from a “continuing dialogue” between “lawmakers, scientists, ethicists, [and] economists” to the creation of specialized science courts.

Although this is a thought provoking article, it suffers from being too short. A longer article or monograph might have allowed a fuller discussion of the ideas the authors raise. Still, it is well worth a read.

## Article Highlights Dispute Over Federal Nano-EHS Research Strategy

An April 2009 article in Environmental Health Perspectives (EHP) highlights the ongoing dispute over the federal government's nano-related environmental, health, and safety (EHS) research strategy. Regular readers will recall that the National Nanotechnology Initiative (NNI) published the 2008 document "Strategy for Nanotechnology-Related Environmental, Health, and Safety Research" which outlined about 250 ongoing federal nano-research projects, identified EHS research gaps, and prioritized future EHS research needs. The EHP article explains that in February 2009, the National Research



Council published its review of the NNI document which was very critical (to put it mildly), and the NNI then posted its rebuttal to the NRC document on its own website. All three documents are well worth reading. Exactly where federally-funded nano-related EHS research in the U.S. is headed (and regulation for that matter) presents complex political as well as scientific issues.

*From C. Schmidt, Environmental Health Perspectives, Nanotechnology-Related Environmental, Health, and Safety Research: Examining the National Strategy (April 2009).*

## Odds & Ends

- The Occupational Safety & Health Administration (OSHA) has launched a dedicated website containing information such as OSHA's definition of nanotechnology, applicable OSHA standards, and workplace health effects related to nanotechnology.
- The International Standards Organization (ISO) released ISO/TR 12885:2008, "Health and safety practices in occupational settings relevant to nanotechnologies." The report "focuses on the occupational manufacture and use of engineered nanomaterials. It does not address health and safety issues or practices associated with nanomaterials generated by natural processes, hot processes and other standard operations which unintentionally generate nanomaterials, or potential consumer exposures or uses, though some of the information in ISO/TR 12885:2008 might be relevant to those areas."
 

The report further states that the "[u]se of the information in ISO/TR 12885:2008 could help companies, researchers, workers and other people to prevent adverse health and safety consequences during the production, handling, use and disposal of manufactured nanomaterials. This advice is broadly applicable across a range of nanomaterials and applications."
- Michael Berger of Nanowerk published an article discussing the adequacy of current regulations in relation to nanomaterials. The article draws heavily from Steffen Foss Hansen's Ph.D thesis, "Regulation and Risk

Assessment of Nanomaterials—Too Little, Too Late?" Mr. Berger uses the thesis to reopen the discussion concerning the adequacy of current regulation as it relates to nanotechnology development.



- An International Medical Device Regulatory article reports that FDA "has no plans to toughen its regulations on nanotechnology." The article quotes Norris Alderson, FDA's Associate Commissioner for Science, as saying, "the science does not dictate that there is a need to do more than what we're already doing now." The article also reports that FDA has no plans to update its 2007 Task Force report and points out that this may be a departure from the recommendations of international counterparts.
- Risk Policy Report indicates that California may be getting ready to move forward on nanotechnology regulation. AB 935 has been proposed, and it is expected that the bill will be amended "to propose a detailed nanotechnology regulatory program for California." As it currently sits, AB 935 is a general, placeholder bill "to state the Legislature's intent to enact legislation to address emerging toxicity issues surrounding the increasingly widespread utilization of engineered nanomaterials."



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